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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,298	02/17/2004	Leo J. Romanczyk JR.	1010/101US14	9721
32260	7590	01/23/2006	EXAMINER	
NADA JAIN, P.C. 560 White Plains Road, Suite 460 Tarrytown, NY 10591			SOLOLA, TAOFIQ A	
			ART UNIT	PAPER NUMBER
			1626	
DATE MAILED: 01/23/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/780,298

Applicant(s)

ROMANCZYK ET AL.

Examiner

Taofiq A. Solola

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 34-80 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 34-80 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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Claims 34-73 is pending in this application.

Request for Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.117(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/12/05 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 35, 80 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification, page 8, 3rd paragraph, incorporated by reference US Application No 09/289,565, for a process of making the gallated and glycosylated derivatives of the instant compound. However, the incorporation is not in accordance with the MPEP, which states as follows:

A mere reference to another application, publication or patent is not an incorporation of anything therein into the application containing such reference for the purpose of satisfying the requirement of 35 USC 112, first paragraph. *In re de Seversky*, 474 F.2d 671, 177 USPQ 144

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(CCPA 1973). Particular attention should be directed to the subject matter and the specific portions of the referenced document where the subject matter being incorporated may be found.

MPEP 608.01(p).

If the document is a pending US application: prior to allowance of an application that incorporates essential material by reference to a pending US application, if the referenced application has not been published or issued as a patent, applicant is required to amend the disclosure of the referencing application to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating the amendment consists of the same material incorporated by reference in the referencing application. MPEP 608.01(p).

Also, the incorporated reference fails to disclose a process of making a glycosylated derivative, gallation or glycosylating process. It discloses only 8-8, 8-6 and 6-6 bonding process between the monomers. Therefore, the specification lacks support for claims 35 and 80. By adding the process the rejection would be overcome. However, addition of new subject matter to the specification would raise the issue of new matter rejection.

Double Patenting Rejection

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

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Claims 34, 36-79 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 209-230 of allowed Application No. 10/127,817. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

In both cases, the claims are drawn to methods of using the same compound for treating atherosclerosis, thrombosis, heart attack, stroke or vascular circulation problem (in 10/127,817), and for anti-platelet therapy in the instant application. However, according to the specification, page 10, lines 31-32, platelet aggregation is involved in the progression of atherosclerosis. Also, on page 14, lines 32-35, the specification discloses that aggregation of platelets leads to thrombus formation (thrombosis), which is responsible for "acute myocardial infarction, unstable angina and percutaneous coronary intervention", and "anti-platelet therapy decrease[s] the incidence of primary and secondary coronary events." Therefore, the claims in the instant application and 10/127,817, are drawn to the same subject matter.

Claims 34, 36-79 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 209-218 of allowed Application No. 10/770,969. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

In 10/770,969, the claims are drawn to methods of using epicatechin and/or catechin for treating atherosclerosis, thrombosis, heart attack, stroke or vascular circulation problem. In the instant application, the claims are drawn to method of using procyanidin for anti-platelet therapy. However, according to the specification, page 2, lines 20-22, "procyanidin [is] selected from epicatechin, catechin, procyanidin B-2, procyanidin oligomers 2-12, preferably 2-14 or 4-12, more preferably 3-12 and most preferably 5-12, procyanidin B-5, procyanidin A-2 and procyanidin C-1." On page 10, lines 31-32, the specification further states that platelet aggregation is involved in the progression of atherosclerosis. Also, on page 14, lines 32-35, the

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specification discloses that aggregation of platelets leads to thrombus formation (thrombosis), which is responsible for "acute myocardial infarction, unstable angina and percutaneous coronary intervention", and "anti-platelet therapy decrease[s] the incidence of primary and secondary coronary events." Therefore, the claims in the instant application and 10/770,969, are drawn to the same subject matter.

Applicant's arguments filed 12/12/05 have been fully considered but they are not persuasive. Applicant contends that the instant compounds are gallated or glycosylated while the compounds of applications US '817 and US '969, are not. This is not persuasive because only claims 35 and 80 involves gallated and glycosylated compounds respectively. Even then gallated and glycosylated compounds lack support in the instant specification as set forth above under 35 USC 112. Applicant also argues that claims 34-80 do not require "cocoa extract, cocoa extract fraction, or cocoa-solids, which are required in claims 222-227 of US '817. This is not persuasive because the specification of US '817 and the instant specification refer to both compositions as cocoa extract, cocoa extract fraction, or cocoa-solids.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD, JD, whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane, can be reached on (571) 272-0699. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

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A handwritten signature in black ink, appearing to read 'Solola', with a stylized flourish at the end.

**TAOFIQ SOLOLA
PRIMARY EXAMINER**

Group 1626

January 18, 2006